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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,892	05/17/2005	Braj B. Lohray	ES/4062-126	1055

23117 7590 09/17/2008
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EXAMINER	
JARRELL, NOBLE E	

ART UNIT	PAPER NUMBER
1624	

MAIL DATE	DELIVERY MODE
09/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/509,892	LOHRAY ET AL.	
	Examiner	Art Unit	
	NOBLE JARRELL	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17,21 and 22* is/are pending in the application.

4a) Of the above claim(s) *9,10,16 and 17* is/are withdrawn from consideration.

5)☒ Claim(s) *22* is/are allowed.

6)☒ Claim(s) *1,3-8,14,15 and 21* is/are rejected.

7)☒ Claim(s) *2 and 11-13* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/17/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. The objections to the specification have been overcome by the amendment filed 6/17/2008.

2. The rejections under 35 U.S.C. 112 1st paragraph have been overcome by the amendment filed 6/17/2008.

3. The objections of claim 6 being a duplicate of claim 1 and claim 18 being a duplicate of claim 6 have been overcome by the amendment filed 6/17/2008.

4. Claims 1-17 and 21-22 are pending in the instant application. Claims 9-10 and 16-17 are considered withdrawn. Thus, claims 1-15 and 21 are being examined in this office action.

Claim Objections

5. Claims 1-3, 5-15, and 21 are objected to because of the following informalities: they contain non-elected subject matter. Variable Ar can only be a phenyl ring. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-8 and 11-15 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The "thio" group for variables R^1 through R^4 appears to be a dangling valence. What is the sulfur atom attached to? What groups act as substituents for alkyl, aralkyl, alkoxy, thio, amino, aminoalkyl, thioalkoxy, cycloalkyl, haloalkyl, and haloalkoxy groups of variables R^1 and R^2? What groups act as substituents for cycloalkyl, alkoxy, cycloalkoxy, aryl, aryloxy, aralkyl, aralkoxy, acyl, acyloxy, and every other substituted group for

variables R^3 and R^4? If the dotted line of page 66 represents a bond, then groups G_2 and G_3 can only have two variables attached (because it will be an alkyne).

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 14-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of bacterial infections caused by Gram positive bacteria, does not reasonably provide enablement for treatment of psoriasis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Pharmacia and Upjohn (WO9925344, published 27 May 1999, classified as A61K31/42) teach that psoriasis has no known etiology, and therefore it cannot be treated or prevented (page 1, lines 11-31).

> The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in Wands states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (*Wands*, 8 USPQ2sd 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (*Wands*, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Consideration of the relevant factors sufficient to establish a *prima facie* case for lack of enablement is set forth herein below:

(1) The nature of the invention and (2) the breadth of the claims:

The claims are drawn to a method of treating bacterial infections caused by Gram positive bacteria using compounds with a piperidine-phenyl-oxazolidinone core structure. Thus, the claims taken together with the specification imply that these compounds can treat bacterial infections caused by Gram positive bacteria by inhibition of bacterial growth.

(3) The state of the prior art and (4) the predictability or unpredictability of the art:

Pharmacia and Upjohn (WO9925344, published 27 May 1999, classified as A61K31/42) teach that psoriasis has no known etiology, and therefore cannot be treated or prevented (page 1, lines 11-31).

(5) The relative skill of those in the art:

Those of relative skill in the art are those with level of skill of the authors of the references cited to support the examiner's position. The relative skill of those in this art is MD's, PhD's, or those with advanced degrees and the requisite experience in treatment of psoriasis or treatment of Gram-positive bacteria caused bacterial infections.

(6) The amount of direction or guidance presented and (7) the presence or absence of working examples:

The specification has provided guidance for treatment of Gram-positive bacteria caused bacterial infections.

However, the specification does not provide guidance for treatment of psoriasis.

(8) The quantity of experimentation necessary:

Considering the state of the art as discussed by the references above, particularly with regards to claims 14-15 and the high unpredictability in the art as evidenced therein, and the

lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to practice the invention commensurate in the scope of the claims.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims 1, 3-8, 14-15, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harris (US20040204463, published October 24, 2004, claims priority to 60/459444, filed April 1, 2003).

Determining the scope and contents of the prior art

Harris teaches the preparation of compound 21 in example 17. In compound 21, variable Y is an obvious variant of group G_2, $C(O)$-$(CH_2)_2$-phenyl-4-CH_2-$CH(NH_2)$-CO_2Me. Variable W is NH-acetyl. Compounds prepared by Harris are being used as antibacterial agents (see abstract). In paragraph 0060, Gram positive bacteria are cited as bacteria which can be acted on compound 21. Compositions are taught on page 4, paragraphs 0089-0094.

Ascertaining the differences between the prior art and the claims at issue

In the prior art, the linker between the C(O) and C=C or alkyne group is a $(CH_2)_2$ group. In the instant application, the linker between the C(O) and C=C or alkyne group in group G_2 is a $(CH_2)_1$ group.

Resolving the level of ordinary skill in the pertinent art

One of ordinary skill in the art can make a compound where the linking group is a CH_2 or $(CH_2)_2$ group.

Considering objective evidence present in the application indicating obviousness or nonobviousness

Sterling Drug Inc. v. Watson, Comr. Patents (108 USPQ 37) teaches that the test in determining patentability of a compound that is a homologue of another is whether its beneficial characteristics are both unexpected and unobvious. In the comparison of the prior art and the instant application, the insertion of a methylene group does not affect the ability of a compound to act as an antibacterial agent. Thus, Harris is obvious over the instant application.

Conclusion

13. Claim 22 appears free of the prior art.

14. The following is a statement of reasons for the indication of allowable subject matter: Harris does not teach the derivation of a CH_2-W group from a CH_2-L (where L is a leaving group) to a CH_2-W group. In claim 22, this transformation is done through several different methodologies. Harris teaches the preparation of example 17 from a compound where CH_2W is $CH_2NC(O)Me$. In addition, Harris foes not use DCC or HOBT when R is OH.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NOBLE JARRELL whose telephone number is (571)272-9077. The examiner can normally be reached on M-F 7:30 A.M - 6:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Noble Jarrell/
Examiner, Art Unit 1624

/James O. Wilson/
Supervisory Patent Examiner, Art Unit 1624